

Guidance for Industry Advisory Committee Meetings — Preparation and Public Availability of Information Given to Advisory Committee Members

DRAFT GUIDANCE

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For questions regarding this draft document contact the Office of Policy (Office of the Commissioner) at 301-827-3360.

**U.S. Department of Health and Human Services
Food and Drug Administration**

February 2007

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**U.S. Department of Health and Human Services
Food and Drug Administration**

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I.	INTRODUCTION.....	4
II.	BACKGROUND	5
A.	RELEVANT STATUTES AND REGULATIONS	5
B.	ADVISORY COMMITTEE MEETINGS – GENERAL INFORMATION.....	5
III.	MAKING BRIEFING MATERIALS AVAILABLE TO THE PUBLIC	6
A.	SCOPE OF BRIEFING MATERIALS SUBJECT TO THIS GUIDANCE	6
B.	TIMELINES FOR SUBMITTING AND MAKING BRIEFING MATERIALS PUBLICLY AVAILABLE	6
C.	POSTPONING THE PUBLIC RELEASE OF BRIEFING MATERIALS	8
IV.	PREPARING BRIEFING MATERIALS	8
A.	GENERAL RECOMMENDATIONS ON PREPARING BRIEFING MATERIALS.....	8
B.	INFORMATION IN BRIEFING MATERIALS THAT TYPICALLY WILL BE DISCLOSABLE UNDER FOIA...	9
C.	INFORMATION IN BRIEFING MATERIALS THAT WILL TYPICALLY BE EXEMPT FROM DISCLOSURE .	10
D.	FULLY RELEASABLE SPONSOR BRIEFING MATERIALS	11
E.	SPONSOR BRIEFING MATERIALS THAT CONTAIN INFORMATION CLAIMED TO BE EXEMPT FROM DISCLOSURE.....	11
F.	FDA-PREPARED ADVISORY COMMITTEE BRIEFING MATERIALS	13
G.	POSTING BRIEFING MATERIALS ON FDA’S WEB SITE	14
	APPENDIX A. TIMELINE FOR OPEN FDA ADVISORY COMMITTEE MEETINGS INVOLVING FDA BRIEFING MATERIALS AND SPONSOR BRIEFING MATERIALS THAT ARE FULLY RELEASABLE	17
	APPENDIX B. TIMELINE FOR OPEN FDA ADVISORY COMMITTEE MEETINGS INVOLVING FDA BRIEFING MATERIALS AND SPONSOR BRIEFING MATERIALS THAT ARE NOT FULLY RELEASABLE	19

Guidance for Industry¹

Advisory Committee Meetings — Preparation and Public Availability of Information Given to Advisory Committee Members

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This document provides guidance to industry sponsors, applicants, and petitioners (referred to collectively as *sponsors*) who develop, prepare, or submit briefing materials that will be given to advisory committee members as background information before an open FDA advisory committee meeting.² This guidance will help sponsors develop, organize, and submit advisory committee briefing materials for public release and should help minimize the time and resources spent in preparing these materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public. In addition, the Appendices provide recommended timelines for preparing and submitting briefing materials to us.³

An important goal of this guidance is to help ensure that briefing materials are made available to the public as provided under section 10(b) of the Federal Advisory

¹ This guidance has been prepared by a working group with members from across FDA.

² Most FDA advisory committee meetings are open to the public. However, sometimes a portion of a meeting will be closed to the public under 21 C.F.R. § 14.27. This guidance only applies to briefing materials prepared for open advisory committee meetings or for the open portions of such meetings.

³ This draft guidance, which applies to all FDA open advisory committee meetings or open portions of such meetings, replaces three previously issued draft guidances: 1) Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research (CDER), Beginning on January 1, 2000 (December 1999); 2) Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research (CBER) (February 2001); and 3) Availability of Information Given to Advisory Committee Members in Connection with the Center for Devices and Radiological Health (CDRH) Open Public Panel Meetings (July 2001).

Committee Act (FACA) (5 U.S.C. App. 2). The guidance includes recommendations on how to identify information that is exempt from public disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. § 552).

Our guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Relevant Statutes and Regulations

As stated earlier, under section 10(b) of FACA, any materials made available to an advisory committee also must be made available to the public. The public availability of these materials, however, is subject to FOIA, and FOIA exempts certain types of information from public disclosure. We interpret FACA to require that, with respect to any open advisory committee meeting convened pursuant to FACA, whenever practicable and subject to any applicable FOIA exemptions, those materials that we provide to advisory committee members in connection with that meeting must be made available for public inspection and copying *before or at the time of* the advisory committee meeting.

Several FDA regulations (e.g., 21 CFR §§ 20.61, 20.63, 171.1, 314.430, 514.12, 601.51, and 860.5) protect information that is exempt from public disclosure under FOIA. We interpret our regulations to be consistent with FACA and intend to exercise our discretion under our regulations in a manner consistent with FACA and FOIA. This guidance should help ensure that information that is exempt from disclosure under FOIA will not be made publicly available.

B. Advisory Committee Meetings – General Information

III.

We convene advisory committee meetings for a variety of different purposes. Some meetings discuss particular matters such as the approval or testing of products. Topics commonly discussed at this type of advisory committee meeting often involve marketing applications/submissions such as:

- New drug applications and application supplements;
- New animal drug applications and application supplements;
- Biologics license applications and application supplements;
- Premarket approval applications for medical devices and their supplements;
- Premarket notifications for medical devices; and

- Medical device classifications and reclassifications.

We also convene advisory committee meetings to discuss general matters, such as guidance documents, issues pertaining to trial design, post-approval monitoring, citizen's petitions, and policy issues related to FDA-regulated products.

III. MAKING BRIEFING MATERIALS AVAILABLE TO THE PUBLIC

A. Scope of Briefing Materials Subject to this Guidance

This guidance uses the term “briefing materials” to describe the package of information that we provide to advisory committee members before a meeting. The briefing materials usually contain information prepared by us and/or the sponsor (if the meeting involves an application or a particular product). Although interested persons (i.e., individuals or organizations who are not sponsors) may submit information to an advisory committee pursuant to 21 C.F.R. §§ 14.29 or 14.35(d), this guidance does not consider those submissions to be “briefing materials.”⁴

B. Timelines for Submitting and Making Briefing Materials Publicly Available

For an open advisory committee meeting for which the briefing materials may contain information that, under certain circumstances, could be considered to be exempt from public disclosure under FOIA, we intend to post a publicly available version of the briefing materials on our Web site at least *two full business days*⁵ before the advisory committee meeting is scheduled to occur. With respect to meetings for which the briefing materials do not contain information that, under certain circumstances, could be considered exempt from public disclosure under FOIA, we will probably make the briefing materials available on our Web site more than two full business days before the advisory committee meeting is scheduled to occur. We anticipate that meetings subject to this timeline will normally address general matters such as guidance documents and policy issues related to FDA-regulated products.

Whether the briefing materials for a particular advisory committee meeting are subject to the timelines in the Appendices, or will probably be posted on our Web site more than two full business days before the advisory committee meeting is scheduled to occur, does not depend on whether they are fully releasable without redaction (see section IV.D). Rather, it depends on whether they contain information that, under certain circumstances, could be considered to be exempt from disclosure under FOIA. For example, if a sponsor prepares briefing materials for an advisory committee meeting on a pending application,

⁴ Information submitted by interested persons is considered to be publicly disclosable and must conform to the requirements of 21 CFR § 10.20. Failure to comply with the requirements will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply (21 CFR § 10.20(c)(6)).

⁵ In this guidance, a “business day” is a day that we are officially open for business.

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the fact that the sponsor submits briefing materials that do not contain any information that it asserts is exempt from disclosure under FOIA) (see section IV.B) does not mean that those materials will be posted on our Web site earlier than they would have been if the sponsor included in them information that it does assert is exempt from disclosure under FOIA (see section IV.E). As another example, if we prepare briefing materials for an advisory committee meeting on a policy issue, and include publicly available information related to one or more specific products, we will probably make those briefing materials available on our Web site more than two full business days before the advisory committee meeting is scheduled to occur.

If an advisory committee meeting is scheduled to address more than one topic, separate briefing materials may be prepared for the different topics on the meeting agenda. For meetings that last more than one day, we intend to post the publicly available version of the briefing materials on our Web site at least two full business days before the topic to which the materials pertain will be discussed. For example, assume that two drugs, A and B, will be discussed on days 1 and 2 respectively. We would make the briefing materials on drug A available at least two full business days before the scheduled day 1 of the advisory committee meeting and the briefing materials on drug B available at least two full business days before the scheduled day 2 of the advisory committee meeting. Please note that the timelines for sponsors to submit materials to us are linked to the first day of the meeting and not to the specific day on which a particular topic will be discussed. Thus, in our example, the sponsor for drug B would have the same deadline for submitting materials to us as the sponsor for drug A, even though the discussions for their drugs would occur on different days.

The Appendices to this guidance provide timelines for preparing and submitting briefing materials to us. Appendix A provides timelines for FDA-prepared briefing materials and sponsor-prepared briefing materials that are fully releasable to the public. Appendix B provides timelines for similar briefing materials that are not fully releasable. Please note that the timelines in the Appendices do not provide for formal predisclosure notification to sponsors pursuant to 21 CFR § 20.61(e) and (f). The predisclosure notification requirements in that regulation apply only where the disclosure is to be made in response to a specific request for our records. The disclosures contemplated here are not made in response to a request for our records, but to comply with FACA. Nevertheless, the timelines in the Appendices are at least as generous as the timeframes for notification under 21 CFR § 20.61.

This guidance does, however, constitute public notice under 21 CFR §14.35(d)(2) that a sponsor should submit information to us within the timelines listed in the Appendices if the sponsor wants the advisory committee to consider that information before the meeting. If we do not receive a sponsor's briefing materials within the applicable timeline in the Appendices, we do not intend to provide the sponsor's briefing materials to the members of the committee, and the committee will not consider the sponsor's materials before the meeting.

C. Postponing the Public Release of Briefing Materials

On occasion, the issue of whether certain information in the briefing materials should be made available to the public may need to be decided in court. If a federal court directs us to not release information in briefing materials, we will not release that information and may postpone the advisory committee meeting where the information would have been discussed until the matter is resolved.

IV. PREPARING BRIEFING MATERIALS

The contents of the briefing materials provided to advisory committee members for their review in advance of a meeting differ from meeting to meeting, and the type and amount of information included generally will depend on the type of product or issues to be discussed. Additionally, as indicated in the Appendices, the times by which sponsors should submit briefing materials differ depending on whether the materials contain information that the sponsor claims is exempt from disclosure under FOIA.

It is important to minimize the time we will need to spend reviewing briefing materials, consulting with sponsors, and redacting such materials. The more time we need to complete this process, the earlier the sponsors may need to submit materials for an advisory committee meeting. If the preparation of the materials occurs too far in advance of a meeting, the materials may not adequately address the issues that will be the subject of the meeting because those issues will not yet have been fully identified.

A. General Recommendations on Preparing Briefing Materials

For open advisory committee meetings that involve sponsor-prepared briefing materials, approximately *11 weeks* before the meeting is scheduled to occur, FDA intends to notify a sponsor that an advisory committee will consider an issue that is directly relevant to the sponsor. We will explain the meeting's focus to the sponsor and also may advise the sponsor about the information it may wish to include in its briefing materials. To facilitate the review and eventual posting of sponsor-prepared briefing materials, we strongly recommend that sponsors submit both paper and electronic versions of their materials. Sponsors should consult the appropriate FDA component about compatible electronic formats and consult the Designated Federal Official⁶ for a given meeting to determine the appropriate number of paper copies.⁷

⁶ The Designated Federal Official is a federal employee who is responsible for the overall administrative management of an advisory committee.

⁷ If an advisory committee meeting involves advisory committees from different agency components (e.g., a joint meeting of a Center for Biologics Evaluation and Research advisory committee and a Center for Drug Evaluation and Research advisory committee), sponsors should consult the relevant Designated Federal Officials of the two committees as to the Designated Federal Official coordinating the briefing material process.

We emphasize that a sponsor's submissions should include only information related to the issue being discussed by the committee. Statements or suggestions that could be viewed as misleading or promotional (e.g., statements that go beyond study conclusions or speculate about clinical or commercial implications not supported by the data) are inappropriate for inclusion in the briefing materials. In addition, statements or language that are defamatory, irrelevant, or intemperate are inappropriate for inclusion in briefing materials and should be avoided.

B. Information in Briefing Materials That Typically Will Be Disclosable Under FOIA

We generally will consider the following information in advisory committee briefing materials to be disclosable without redaction, unless the sponsor demonstrates that disclosure of the information is likely to cause substantial competitive harm:

- Summaries of clinical safety and effectiveness data;
- Summaries of non-clinical safety and effectiveness data;
- Summaries of adverse drug reaction data;
- Written discussion or analysis of safety or effectiveness data relevant to the topic of the meeting;
- A general description (such as that which would typically be included in product labeling) of product functions, mechanics, and/or engineering;
- A general description of physical characteristics and performance parameters;
- Clinical or preclinical protocols or summaries of protocols;
- Statistical protocols and analyses;
- Information that is proposed to be included in product labeling, such as indications and usage, dosage and administration, and safety information such as warnings and precautions;
- Literature references;⁸
- Any other information that has been previously publicly disclosed by the sponsor;
- Copies of the sponsor's slides to be presented at the advisory committee meeting, if included in the briefing materials; and

⁸ FDA does not post copyrighted materials on its Web site. If sponsors do wish to submit copyrighted materials, they should provide a bibliography of the copyrighted materials that can be posted.

- Guidance documents.

The above list is neither exhaustive nor absolute.

With regard to certain topics discussed at advisory committee meetings (for example, issues relating to the approval of a pending New Drug Application (NDA), Biologics Licensing Application (BLA), Premarket Approval Application (PMA), 510(k), New Animal Drug Application (NADA), or a supplement to any of these), some of the information listed above might be considered confidential commercial information at earlier stages of the product development process. However, we believe it is appropriate to make this information available under 21 CFR §§ 20.82, 314.430(d)(1), 514.11(d), 601.51(d)(1), 814.9(d)(1), and/or 171.1(h)(2) (whichever is applicable) at the time of an advisory committee meeting if the information is germane to the issues to be discussed at the meeting. These materials are often necessary to a committee's consideration of the safety and effectiveness of a product being discussed and committees and sponsors routinely discuss such matters at open advisory committee meetings. It is widely understood that, when advisory committees consider such products, the information contained in these materials will be the subject of open discussion.

C. Information in Briefing Materials That Will Typically Be Exempt from Disclosure

We generally will consider the following types of information to be exempt from disclosure under FOIA:

- Information about product functions, mechanics, engineering, and schematic drawings not in the proposed labeling and not within the scope of the agenda for the meeting;
- Proprietary physical characteristics and performance parameters not in the proposed labeling and not within the scope of the agenda for the meeting;
- Manufacturing process information;
- Manufacturing quality control information;
- Clinical raw data;⁹
- Non-clinical raw data;
- Supplier names, customer lists, production costs, inventory information, failure rates of products, production quality control information;

⁹ For the purposes of this guidance, FDA considers "raw data" to be a complete data set of case report forms, case report tabulations, or line listings. Data that summarize individual or multiple subject outcomes or results are considered summaries. Summaries may include examples of specific findings.

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- Information for which the release would constitute an unwarranted invasion of personal privacy; and
- Product formulation information not in the labeling.

The above list is neither exhaustive nor absolute.

The advisory committee members will receive complete copies of the briefing materials, including information that is exempt from disclosure under FOIA. However, we will not include information that is exempt from disclosure under FOIA in the publicly available version of the briefing materials, and we will notify the committee members that such exempt information may not be discussed during any open portion of the advisory committee meeting.

D. Fully Releasable Sponsor Briefing Materials

To shorten the process for complying with FACA's disclosure requirements, we strongly encourage sponsors to submit briefing materials that may be released to the public in their entirety without redaction (i.e., that do not contain any information that the sponsor asserts is exempt from disclosure under FOIA). Sponsors also benefit from preparing fully releasable briefing materials because such briefing materials eliminate the need for us to redact trade secret and/or confidential commercial information and, as a result, can be submitted to us closer in time to the advisory committee meeting than briefing materials containing information that the sponsor asserts is exempt from disclosure under FOIA. As a result, sponsors may be able to devote more time to preparing their submissions before the advisory committee meeting occurs (see timelines in the Appendices).

If a sponsor chooses to submit fully releasable briefing materials, it should mark the materials as: “*Advisory Committee Briefing Materials: Available for Public Release.*”

When we receive briefing materials marked as fully releasable, we will review the materials for completeness. We will assume that sponsors who mark their materials “Available for Public Release” have carefully reviewed the included materials to make sure that they all may be made available to the public without redaction. Sponsors should not expect us to identify trade secret or confidential commercial information in briefing materials marked as “Available for Public Release.” We will, however, review sponsor briefing materials for information that, if publicly released, would constitute a clearly unwarranted invasion of personal privacy, and we will redact such information.

E. Sponsor Briefing Materials that Contain Information Claimed to be Exempt from Disclosure

A sponsor may elect to prepare advisory committee briefing materials that contain information that it believes is exempt from disclosure under FOIA (see section IV.C. for a discussion of what types of information we generally will consider to be exempt from

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disclosure). If the sponsor chooses to prepare such briefing materials, it should prepare two versions of its briefing materials at the same time. One version should be complete, and should include the information that the sponsor believes should not be available for public release. The second version should be a publicly releasable version.

We recommend that, when preparing briefing materials that contain information the sponsor believes is exempt from disclosure, the sponsor should segregate the information it believes is exempt from disclosure from the releasable information (e.g., by placing it in a separate portion of the briefing materials) or clearly identify the specific information that it believes is exempt from disclosure.

The complete version of the briefing materials (that is, the one that would not be available for public release because it includes the information the sponsor believes is exempt from disclosure under FOIA) should be clearly marked as: *“Draft: Advisory Committee Briefing Materials: Not for Public Release: Contains Trade Secret and/or Confidential Commercial Information.”*

For the version of the briefing materials that would be publicly releasable, the sponsor should prepare and submit a copy of the *same* materials as are included in the version that is not for public release, but this version should indicate what information the sponsor believes is exempt from disclosure under FOIA. Sponsors should indicate the information they believe is exempt by providing a redacted copy. We suggest that, when redacting information, sponsors should identify any proposed deletions and indicate exactly how much material should be redacted. Sponsors can indicate the amount of information that has been removed in several ways. For example, a sponsor could include a statement such as “two paragraphs have been deleted,” or “five pages have been removed.” For each document or portion of a document that the sponsor believes is exempt from disclosure under FOIA, the sponsor should explain, in detail, why it believes that the information is exempt from disclosure under FOIA. We caution that, to the extent that the sponsor intends to discuss specific information during the open portion of the meeting, it will be difficult for the sponsor to claim that the information is exempt from disclosure under FOIA.

Sponsors should label the redacted copy prominently as: *“Draft: Advisory Committee Briefing Materials: Available for Public Release.”*

After we receive the two versions of the briefing materials (the non-public and publicly releasable versions), we will review the briefing materials for completeness and determine if the sponsor appropriately identified exempt information. If we disagree that any of the information the sponsor has redacted is exempt from disclosure under FOIA, we will discuss the matter with the sponsor. When the discussions are concluded, we will notify the sponsor of our final decision. Once we have notified the sponsor of our final decision, no new documents or information may be added to the briefing materials. See the Appendices for details on the timing of this process.

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When the sponsor receives our final decision regarding what information, if any, we have determined to be exempt from disclosure under FOIA, the sponsor has four options:

- **Option 1:** The sponsor may remove from the briefing materials information that we have determined is not exempt from disclosure under FOIA and thus would not be redacted from the materials. The sponsor may reformat the materials accordingly.
- **Option 2:** If the sponsor accepts our determination as to the releasability of the information in the briefing materials, and there is still information in the materials that we and the sponsor agree is exempt from disclosure, the sponsor may submit a final copy of both versions of the briefing materials. The final documents should be prominently labeled: “*Final: Advisory Committee Briefing Materials: Not for Public Release: Contains Trade Secret and/or Confidential Commercial Information*” and “*Final: Advisory Committee Briefing Materials: Available for Public Release.*”
- **Option 3:** If we and the sponsor agree that no information in the materials is exempt from disclosure under FOIA, then the sponsor should submit a copy marked “*Final: Advisory Committee Briefing Materials: Available for Public Release.*”
- **Option 4:** If the sponsor disagrees with our determination regarding the releasability of information in the briefing materials, the sponsor may seek judicial review in federal court to prevent us from releasing the information. If the sponsor chooses this option, we will not release the information that is in dispute and may postpone the advisory committee meeting where the information would be discussed until the matter is resolved.

When this process is complete, we will send the final unredacted version of the sponsor-prepared briefing materials to the advisory committee members in preparation for the scheduled meeting. We will identify any information in the materials that is exempt from disclosure under FOIA for the advisory committee members, and we will advise them that such exempt information may not be discussed during any open portion of the advisory committee meeting. Additionally, the sponsor should not discuss any information which we and the sponsor agree is exempt from disclosure under FOIA at any open portion of the advisory committee meeting.

F. FDA-Prepared Advisory Committee Briefing Materials

For most advisory committee meetings, we prepare our own briefing materials and send them to the advisory committee members. When we have prepared our briefing materials, we will review them to determine if they contain information that, under certain circumstances, could be considered to be exempt from disclosure under FOIA

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(specifically, confidential commercial or trade secret information belonging to a sponsor). If the materials do not contain information that, under certain circumstances, could be considered to be confidential commercial or trade secret information belonging to a sponsor, the portions of the timelines (see Appendices) that pertain to sharing our briefing materials with sponsors will not apply. As discussed in section III.B., we may post such briefing materials on our Web site earlier than two full business days before an advisory committee meeting is scheduled to occur.

If we determine that the briefing materials contain information that, under certain circumstances, could be considered to be confidential commercial or trade secret information belonging to a sponsor, the timelines in the Appendices will apply, and we will send our briefing materials to the sponsor as described in the timelines. If the briefing materials include information pertaining to more than one sponsor, we will send only the relevant portion to each sponsor. We will discuss with each sponsor any disagreements it may have about the disclosability of information in the materials. When these discussions are concluded, we will notify each sponsor of our final decision regarding the public availability of the information in our briefing materials. If the sponsor disagrees with our determination regarding the releasability of information in our briefing materials, the sponsor may seek judicial review in federal court to prevent us from releasing the information. If the sponsor chooses this option, we will not release the information that is in dispute and may postpone the advisory committee meeting where the information would be discussed until the matter is resolved.

G. Posting Briefing Materials on FDA's Web Site

We will post the briefing materials for an open advisory committee meeting subject to this guidance on our Web site at <http://www.fda.gov/ohrms/dockets/ac/acwhatsnew.htm>. The materials also will be available in hard copy at our Division of Dockets Management's Public Reading Room.¹⁰ We will post only the publicly available sponsor-prepared briefing materials and the publicly available FDA-prepared briefing materials on our Web site.

To avoid any misunderstanding that we have endorsed the contents of a sponsor's briefing materials by posting them on our Web site, we will display the following statement with the sponsor's briefing materials placed on our Web site:

"The statements contained in this document are those of the product's sponsor. FDA does not necessarily agree with the sponsor's statements. FDA has not made a final determination about the issues described in this document".

¹⁰ The Public Reading Room is open Monday through Friday, 9:00 a.m. to 4:00 p.m. The Public Reading Room is located at 5630 Fishers Lane, Room 1061, Rockville, Maryland 20857.

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We also may take appropriate action to address any information that may be promotional or misleading, including posting a correction on our Web site.

Please note that if unforeseen difficulties prevent us from posting the briefing materials on our Web site before an advisory committee meeting, we will make hard copies available to the public at the time of the advisory committee meeting.

If you have questions, please refer to the contact information listed below.

- **For briefing materials pertaining to the Center for Biologics Evaluation and Research:**

Office of Communication, Training, and Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200N
Rockville, MD 20852
Phone: 301-827-1800

- **For briefing materials pertaining to the Center for Devices and Radiological Health:**

Freedom of Information Officer, Joy Lazaroff
Office of Management Operations
Division of Ethics and Management Operations, HFZ-23
Center for Devices and Radiological Health
7520 Standish Place
Rockville, MD 20855
Phone: 301-827-7258

- **For briefing materials pertaining to the Center for Drug Evaluation and Research:**

Advisors and Consultants Staff, HFD-21
Center for Drug Evaluation and Research
5630 Fishers Lane, Room 1093
Rockville, MD 20850
Phone: (301) 827-7001

- **For briefing materials pertaining to the Center for Food Safety and Applied Nutrition:**

Freedom of Information Officer, Patricia Gee
Executive Operations Staff, HFS-22
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway

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College Park, MD 20740-3835
Phone: 301-436-2121

- **For briefing materials pertaining to the Center for Veterinary Medicine:**

Freedom of Information Officer, Marilyn Broderick
Communications Staff, HFV-12
Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855
Phone: 240-276-9107

- **For briefing materials pertaining to the National Center for Toxicological Research:**

Rose Huber
Office of the Director, HFT-1
National Center for Toxicological Research
3900 NCTR Road
Jefferson, AR 72079
Phone: 870-543-7130

- **For briefing materials pertaining to the Office of the Commissioner:**

Carlos Peña, PhD, MS
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, HF-33
Rockville, MD 20857
Phone : 301-827-3340

Appendices

APPENDIX A: TIMELINE FOR OPEN FDA ADVISORY COMMITTEE MEETINGS INVOLVING FDA BRIEFING MATERIALS AND SPONSOR BRIEFING MATERIALS THAT ARE FULLY RELEASABLE

FDA Action	Business Days Before Meeting	Sponsor Action
	22	The sponsor should submit its briefing materials to the appropriate agency staff.
We will conduct the following activities: <ul style="list-style-type: none">• We will review the sponsor-prepared briefing materials for completeness.• We will review both the sponsor and final agency briefing materials for disclosure.<ul style="list-style-type: none">○ We will send the complete (unredacted) agency briefing materials to the advisory committee members.○ We will send a copy of our briefing materials (or relevant portions thereof), as prepared for public release, to the sponsor to review.	21 through 14	
We will discuss with the sponsor any concerns it has regarding the disclosability of any information in our briefing materials.	13 through 9	<p>The sponsor will review our briefing materials (or relevant portions thereof), as prepared for public release.</p> <p>The sponsor will discuss with appropriate center staff any concerns it has regarding the disclosability of any information in our briefing materials.</p> <p>The sponsor will inform us whether it disagrees with us regarding the disclosability of any information in our briefing materials.</p>
<p>We will inform the sponsor of our final decision regarding the redaction, if any, of our briefing materials.</p> <p>We will submit both the sponsor's and the agency's briefing materials to our Division of Dockets Management for posting on our Web site.</p>	7	
We will post on our Web site the sponsor's publicly available briefing materials and our	At least 2 full business days	

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FDA Action	Business Days Before Meeting	Sponsor Action
publicly available briefing materials.	before the day on which the sponsor's topic will be discussed	

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APPENDIX B: TIMELINE FOR OPEN FDA ADVISORY COMMITTEE MEETINGS INVOLVING FDA BRIEFING MATERIALS AND SPONSOR BRIEFING MATERIALS THAT ARE NOT FULLY RELEASABLE

FDA Action	Business Days Before Meeting	Sponsor Action
We intend to notify the sponsor that we are taking an issue directly relevant to the sponsor to an advisory committee.	55	
	42	The sponsor will submit two versions of its briefing materials: a complete (unredacted) version and a redacted version.
We will send copies of both the complete (unredacted) and the redacted sponsor's submissions to the appropriate disclosure staff and a copy of the complete sponsor submission to the appropriate review staff.	41	
We will inform the sponsor whether we agree with the sponsor's proposed redactions to the sponsor's briefing materials.	34	
We will discuss redaction of sponsor's briefing materials with the sponsor.	30	The sponsor will discuss redaction of the sponsor's briefing materials with us.
We will inform the sponsor of our final decision regarding the redaction of information from the sponsor's briefing materials.	28	The sponsor will decide whether to remove any materials that we have decided will not be redacted and to reformat the materials accordingly. No new documents or information may be added to the briefing materials at this time.
See Appendix A for Days 22 through 2.	22 through 2	